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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,492	12/04/2001	Rango Dietrich	24826	6447
34375 7590 10/11/2007 NATH & ASSOCIATES PLLC 112 South West Street Alexandria, VA 22314			EXAMINER SHEIKH, HUMERA N	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 10/11/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 09/980,492	Applicant(s) DIETRICH ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All    b) ☐ Some \*    c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Response after Non-Final Office Action, the Amendment, Applicant's Arguments/Remarks and the request for extension of time (1 month-granted), all filed 07/24/07 is acknowledged.

Upon further review and consideration, the previous Non-Final Office Action filed 03/26/07 has been withdrawn. The following are the new grounds of rejection:

Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are pending in this action. Claims 18, 37, 38 and 40 have been amended. Claims 1-10, 12, 15-17, 21-32, 42, 43, 45-49, 56 and 59 have been cancelled. Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are rejected.

### ***Claim Rejections - 35 USC § 112***

#### ***New Matter***

Applicant's recitation of "*wherein the microsphere does not comprise an enteric coating*" in instant claims 11 & 18 presents new matter since there is lack of support for this limitation in the present specification. While the limitation "*the acid-labile active compound does not have to be protected by an enteric coating*" is supported by the instant disclosure at page 3, first paragraph, the limitation "*wherein the microsphere does not comprise an enteric coating*" is not supported by the instant specification. Examiner requests clarification as to where in the instant specification support for the new limitation can be found.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific fatty alcohols disclosed on page 5 of the specification, does not reasonably provide enablement for the generic "fatty alcohol". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants are only enabled for the specific fatty alcohols disclosed on page 5, ¶ 5 of the specification. Namely, Applicants are only enabled for a fatty alcohol that is a linear, saturated or unsaturated primary alcohol having 10-30 carbon atoms. Applicants are non-enabled for all fatty alcohols. The definition of fatty alcohols as presented in the specification (page 5, ¶ 5) should be incorporated into all generic claims.

\* \* \* \* \*

Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the acid-labile compounds being substituted benzimidazoles disclosed on page 4 of the specification, does not reasonably provide enablement for the generic "acid labile active compounds". The specification does not enable any person skilled in the art to which it pertains, or with which it is

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most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants are only enabled for the benzimidazoles listed on page 4, ¶ 7 of the specification. The generic recitation of "acid labile active compounds" recited in the instant claims renders the claims non-enabling. Applicant has only identified the "substituted benzimidazoles" to be useful for their invention. Thus, Applicant's claims should be amended to reflect the particular benzimidazoles as recited on page 4 of the specification.

\* \* \* \* \*

Claims 11, 13, 14, 18-20, 33-41, 44, 50-55, 57, 58 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the examples at pages 14-17, which require the inclusion of a stearylamine and a polymer in addition to the fatty alcohol, does not reasonably provide enablement for the generic "fatty alcohol" *without* inclusion of the stearylamine and polymer. The specification examples demonstrate that the stearylamine and polymer (i.e., povidone) are required to form the active compound units. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants are only enabled for the combination of a fatty alcohol, stearylamine and polymer. The examples demonstrate that the excipients refer to the stearylamine and polymer. The claims must include the presence of stearylamine and polymer, in addition to the fatty alcohol claimed, as this would be enabling. Applicant's claims should be amended to reflect incorporation of all three components of a fatty alcohol, stearylamine and polymer in order to render the claims enabling.

*Response to Arguments*

Applicant's arguments filed 07/24/07 have been fully considered and were found to be partially persuasive.

▪ **35 U.S.C. 112 1<sup>st</sup> paragraph, New Matter Rejection:**

Applicant argued, "The Specification teaches that neither the individual active compound, i.e., that comprising a matrix, which comprises a microsphere, nor the acid-labile active compound, require enteric coating. See the specification at page 3, 1<sup>st</sup> paragraph and paragraph bridging pages 10 and 11. As the acid-labile active compound would not have to be enteric coated, it would follow that the microsphere would not have to be enteric coated".

Applicant's arguments have been considered, but were not found persuasive. The pages of the instant specification referred to by Applicant are not sufficient to overcome the 112, 1<sup>st</sup> paragraph rejection. The specification only states that the "acid-labile active compound does not have to be protected by an enteric coating (page 3, 3<sup>rd</sup> paragraph). Thus, the enteric coating is limited to the exclusion of the coating of the active compound (drug), and is not limited to the microsphere itself that contains the drug. The specification does not support the language that the "microsphere does not comprise an enteric coating".

This rejection has been maintained.

▪ **35 U.S.C. 103(a) over Inagi ('720) in view of Benton ('094):**

Applicant argued, "Applicants note that Inagi et al. is not prior art within the meaning of 35 U.S.C. 103(a) because it is not prior art under the pertinent sections of 35 U.S.C. 102, i.e. 35 U.S.C. §§ 102(a), 102(b), and/or 102(e). Briefly, the present application is a national phase application of an International Application that claims priority to a European Patent Application. The present application was filed as a national phase application in the US on December 4, 2001. The International Application was filed on May 31, 2000. The European Patent Application, to which each of these applications claims priority, was filed on June 7, 1999. Accordingly, under US law, the present application has a priority date of **June 7, 1999.**"

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Applicant's arguments were found to be persuasive. Accordingly, the §103(a) rejection over Inagi in view of Benton has been withdrawn.

### ***Conclusion***

--No claims are allowed at this time.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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October 08, 2007

  
HUMERA N. SHEIKH  
PRIMARY EXAMINER